Handbook of PHARMACEUTICAL EXCIPIENTS

Second Edition

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American Pharmaceutical Association
Washington

The Pharmaceutical Press
London

1994

Polymethacrylates

1. Nonproprietary Names

USPNF: Ammonio methacrylate copolymer
USPNF: Methacrylic acid copolymer
Note that two separate monographs applicable to polymethacrylates are contained in the USPNF, *see* Section 9.

2. Synonyms

Eudragit; polymeric methacrylates.

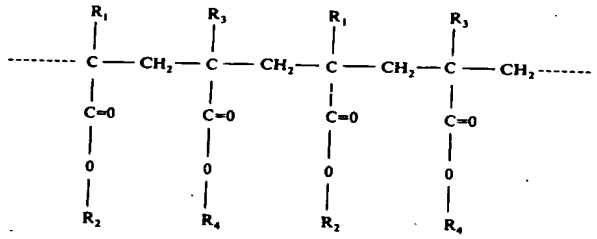
3. Chemical Name and CAS Registry Number

See Table I.

4. Empirical Formula Molecular Weight

The USPNF XVII describes methacrylic acid copolymer as a fully polymerized copolymer of methacrylic acid and an acrylic or methacrylic ester. Three types, type A (*Eudragit L*), type B (*Eudragit S*), and type C (*Eudragit L 30 D-55*), are defined which vary in their methacrylic acid content and solution viscosity. Two additional polymers, type A (*Eudragit RL*) and type B (*Eudragit RS*), also referred to as ammonio methacrylate copolymers, consisting of fully polymerized copolymers of acrylic acid and methacrylic acid esters with a low content of quaternary ammonium groups, are also described in the USPNF XVII. *See* Section 9.
Typically, the molecular weight of the polymer is ≥ 100 000.

5. Structural Formula



For *Eudragit E*:
R_1, R_3 = CH_3
R_2 = $CH_2CH_2N(CH_3)_2$
R_4 = CH_3, C_4H_9
For *Eudragit L* and *S*:
R_1, R_3 = CH_3
R_2 = H
R_4 = CH_3
For *Eudragit RL* and *RS*:
R_1 = H, CH_3
R_2 = CH_3, C_2H_5
R_3 = CH_3
R_4 = $CH_2CH_2N(CH_3)_3^+Cl^-$
For *Eudragit NE 30 D*:
R_1, R_3 = H, CH_3
R_2, R_4 = CH_3, C_2H_5
For *Eudragit L 30 D-55* and *L 100-55*:
R_1, R_3 = H, CH_3
R_2 = H
R_4 = CH_3, C_2H_5

6. Functional Category

Film-former; tablet binder; tablet diluent.

7. Applications in Pharmaceutical Formulation or Technology

Polymethacrylates are primarily used in oral capsule and tablet formulations as film coating agents.[1-10] Depending on the type of polymer used, films of different solubility characteristics can be produced, *see* Table III.
Eudragit E is used as a plain or insulating film former; it is soluble in gastric fluid below pH 5. In contrast, *Eudragit L* and *S* types are used as enteric coating agents since they are resistant to gastric fluid. Different types are available which are soluble at different pH values, e.g. *Eudragit L 100* is soluble at > pH 6, *Eudragit S 100* is soluble at > pH 7.
Eudragit RL, *RS* and *NE 30 D* are used to form water-insoluble film coats for sustained release products. *Eudragit RL* films are more permeable than those of *Eudragit RS*, and by mixing the two types together films of varying permeability can be obtained. *Eudragit L 100-55* is a redispersible powder and is an alternative to *Eudragit L 30 D-55* for aqueous enteric coating.
Polymethacrylates are also used as binders in both aqueous and organic wet-granulation processes. Larger quantities (5-20%) of dry polymer are used to control the release of an active substance from a tablet matrix. Solid polymers may be used in direct compression processes in quantities of 10-50%. Polymethacrylate polymers may additionally be used to form the matrix layers of transdermal delivery systems and have also been used to prepare novel gel formulations for rectal administration.[11]
See also Section 19.

8. Description

Polymethacrylates are synthetic cationic and anionic polymers of dimethylaminoethylmethacrylates, methacrylic acid and methacrylic acid esters in varying ratios. Several different types are commercially available and may be obtained as the dry powder, an aqueous dispersion, or as an organic solution. A (60:40) mixture of acetone and propan-2-ol is most commonly used as the organic solvent. *See* Tables I and II.
Eudragit E is cationic polymer based on dimethylaminoethyl methacrylate and other neutral methacrylic acid esters. It is soluble in gastric fluid as well as in weakly acidic buffer solutions (up to approximately pH 5). *Eudragit E* is available as a 12.5% ready-to-use solution in propan-2-ol/acetone (60:40). It is light yellow in color with the characteristic odor of the solvents. Solvent-free granules contain ≥ 98% dried weight content of *Eudragit E*.
Eudragit L and *S*, also referred to as methacylic acid copolymers in the USPNF monograph, are anionic copolymerization products of methacrylic acid and methyl methacrylate. The ratio of free carboxyl groups to the ester is approximately 1:1 in *Eudragit L* and approximately 1:2 in *Eudragit S*. Both polymers are readily soluble in neutral to weakly alkaline conditions (pH 6-7) and form salts with alkalis, thus affording film coats which are resistant to gastric media but soluble in intestinal fluid. They are available as a 12.5% solution in propan-2-ol without plasticizer (*Eudragit L 12.5* and *S 12.5*); and as a 12.5% ready-to-use solution in propan-2-ol with 1.25% dibutyl phthalate as plasticizer (*Eudragit L 12.5 P* and *S 12.5 P*). Solutions are colorless, with the characteristic odor of the solvent. *Eudragit L-100* and

Table I: Chemical name and CAS registry number of polymethacrylates.

Chemical name	Trade name	CAS number
Poly(butyl methacrylate, (2-dimethyl aminoethyl) methacrylate, methyl methacrylate) 1:2:1	*Eudragit E 100* *Eudragit E 12.5*	[24938-16-7]
Poly(ethyl acrylate, methyl methacrylate) 2:1	*Eudragit NE 30 D* (formerly *Eudragit 30 D*)	[9010-88-2]
Poly(methacrylic acid, methyl methacrylate) 1:1	*Eudragit L 100* *Eudragit L 12.5* *Eudragit L 12.5 P*	[25806-15-1]
Poly(methacrylic acid, ethyl acrylate) 1:1	*Eudragit L 30 D-55* *Eudragit L 100-55*	[25212-88-8]
Poly(methacrylic acid, methyl methacrylate) 1:2	*Eudragit S 100* *Eudragit S 12.5* *Eudragit S 12.5 P*	[25086-15-1]
Poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) 1:2:0.2	*Eudragit RL 100* *Eudragit RL PO* *Eudragit RL 30 D* *Eudragit RL 12.5*	[33434-24-1]
Poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) 1:2:0.1	*Eudragit RS 100* *Eudragit RS PO* *Eudragit RS 30 D* *Eudragit RS 12.5*	[33434-24-1]

Eudragit S-100 are white free flowing powders with at least 95% of dry polymers.

Eudragit RL and *Eudragit RS*, also referred to as ammoniomethacrylate copolymers in the USPNF monograph, are copolymers synthesized from acrylic acid and methacrylic acid esters with *Eudragit RL* (type A) having 10% of functional quaternary ammonium groups and *Eudragit RS* (type B) having 5% of functional quaternary ammonium groups. The ammonium groups are present as salts and give rise to pH-independent permeability of the polymers. Both polymers are water-insoluble, and films prepared from *Eudragit RL* are freely permeable to water, whereas, films prepared from *Eudragit RS* are only slightly permeable to water. They are available as 12.5% ready-to-use solutions in propan-2-ol/acetone (60:40). Solutions are colorless or slightly yellow in color, and may be clear or slightly turbid; they have an odor characteristic of the solvents. Solvent-free granules (*Eudragit RL 100* and *Eudragit RS 100*) contain ⩾ 97% of the dried weight content of the polymer.

Eudragit RL PO and *Eudragit RS PO* are fine, white powders with a slight amine-like odor. They are characteristically the same polymers as *Eudragit RL* and *RS*. They contain ⩾ 97% of dry polymer.

Eudragit RL 30 D and *Eudragit RS 30 D* are aqueous dispersions of copolymers of acrylic acid and methacrylic acid esters with a low content of quaternary ammonium groups. The dispersions contain 30% polymer. The quaternary groups occur as salts and are responsible for the permeability of films made from these polymers. Films prepared from *Eudragit RL 30 D* are readily permeable to water and to dissolved active substances, whereas films prepared from *Eudragit RS 30 D* are less permeable to water. Film coatings prepared from both polymers give pH-independent release of active substance. Plasticizers are usually added to improve film properties.

Eudragit NE 30 D is an aqueous dispersion of a neutral copolymer consisting of polymethacrylic acid esters. The dispersions are milky-white liquids of low viscosity and have a weak aromatic odor. Films prepared from the lacquer swell in water, to which they become permeable. Thus, films produced are insoluble in water, but give pH-independent drug release.

Eudragit L 30 D-55 is an aqueous dispersion of an anionic copolymer based on methacrylic acid and acrylic acid ethyl ester. The polymer corresponds to USPNF methacrylic acid copolymer, type C. The ratio of free carboxyl groups to ester groups is 1:1. Films dissolve above pH 5.5 forming salts with alkalis, thus affording coatings which are insoluble in gastric media, but soluble in the small intestine.

Eudragit L 100-55 (prepared by spray-drying *Eudragit L 30 D-55*) is a white, free-flowing powder which is redispersible in water to form a latex which has properties similar to *Eudragit L 30 D-55*.

9. Pharmacopeial Specifications

Specifications for methacrylic acid copolymers (*Eudragit L, S* and *L 30 D-55*).

Test	USPNF XVII (Suppl 6)
Identification	+
Viscosity	
Type A	50-200 mPa s
Type B	50-200 mPa s
Type C	100-200 mPa s
Loss on drying	
Type A	⩽ 5.0%
Type B	⩽ 5.0%
Type C	⩽ 3.0%
Residue on ignition	
Type A	⩽ 0.1%
Type B	⩽ 0.1%
Type C	⩽ 0.4%
Arsenic	⩽ 2 ppm
Heavy metals	⩽ 0.002%
Monomers	⩽ 0.3%
Assay of methacrylic acid units (dried basis)	
Type A	46.0-50.6%
Type B	27.6-30.7%
Type C	46.0-50.6%

Specifications for ammonio methacrylate copolymers (*Eudragit RL* and *RS*).

Test	USPNF XVII (Suppl 4)
Identification	+
Viscosity	
Types A and B	⩽ 15 mPa s
Loss on drying	
Types A and B	⩽ 3.0%
Residue on ignition	
Types A and B	⩽ 0.1%
Arsenic	⩽ 2 ppm
Heavy metals	⩽ 0.002%
Monomers	⩽ 0.3%
Assay of ammonio methacrylate units (dried basis)	
Type A	8.85-11.96%
Type B	4.48-6.77%

10. Typical Properties

Acid value: 315 for *Eudragit L 12.5*, *L 12.5 P*, *L 100*, *L 30 D-55*, and *L 100-55*; 180-200 for *Eudragit S 12.5*, *S 12.5 P*, and *S 100*.

Alkali value:
162-198 for *Eudragit E 12.5* and *E 100*;
23.9-32.3 for *Eudragit RL 12.5*, *RL 100*, and *RL PO*;
27.5-31.7 for *Eudragit RL 30 D*;
12.1-18.3 for *Eudragit RS 12.5*, *RS 100*, and *RS PO*;
16.5-22.3 for *Eudragit RS 30 D*.
Density:
0.81-0.82 g/cm^3 for *Eudragit E*;
0.83-0.85 g/cm^3 for *Eudragit L*, *S 12.5* and *12.5 P*;
0.83-0.85 g/cm^3 for *Eudragit L*, *S 100*;
1.06-1.07 g/cm^3 for *Eudragit L 30 D-55*;
0.82-0.84 g/cm^3 for *Eudragit L 100-55*;
0.815-0.835 g/cm^3 for *Eudragit RL* and *RS 12.5*;
0.815-0.835 g/cm^3 for *Eudragit RL* and *RS PO*;
1.045-1.055 g/cm^3 for *Eudragit RL* and *RS 30 D*.
Refractive index:
n_D^{20} = 1.38-1.385 for *Eudragit E*;
n_D^{20} = 1.39-1.395 for *Eudragit L* and *S*;
n_D^{20} = 1.387-1.392 for *Eudragit L 100-55*;
n_D^{20} = 1.38-1.385 for *Eudragit RL* and *RS*.
Solubility: *see* Table II.
Viscosity (dynamic):
3-12 mPa s for *Eudragit E*;
50-200 mPa s for *Eudragit L* and *S*;
⩽ 50 mPa s for *Eudragit L 30 D-55*;
100-200 mPa s for *Eudragit L 100-55*;
⩽ 15 mPa s for *Eudragit RL* and *RS*;
⩾ 200 mPa s for *Eudragit RL* and *RS D*.

Table II: Solubility of commercially available polymethacrylates (*Eudragit*, Röhm Pharma GmbH) in various solutions.

Type	Solvent						
	Acetone and alcohols[a]	Dichloromethane	Ethyl acetate	1N HCl	1N NaOH	Petroleum ether	Water
Eudragit E 12.5	M	M	M	M	—	M	—
Eudragit E 100	S	S	S	—	—	I	I
Eudragit L 12.5 P	M	M	M	—	M	P	P
Eudragit L 12.5	M	M	M	—	M	P	P
Eudragit L 100-55	S	I	I	—	S	I	I
Eudragit L 100	S	I	I	—	S	I	I
Eudragit L 30 D-55[b]	M[c]	—	—	—	M[d]	—	M
Eudragit S 12.5 P	M	M	M	—	M	P	P
Eudragit S 12.5	M	M	M	—	M	P	P
Eudragit S 100	S	I	I	—	S	I	I
Eudragit RL 12.5	M	M	M	—	—	P	M
Eudragit RL 100	S	S	S	—	—	I	I
Eudragit RL PO	S	S	S	—	I	I	I
Eudragit RL 30 D	M[e]	M	M	—	I	I	M
Eudragit RS 12.5	M	M	M	—	—	P	M
Eudragit RS 100	S	S	S	—	—	I	I
Eudragit RS PO	S	S	S	—	I	I	I
Eudragit RS 30 D	M[e]	M	M	—	I	I	M

Where: S = soluble;
M = miscible;
I = insoluble or immiscible;
P = precipitates.
Note: a. Alcohols including ethanol, methanol and propan-2-ol.
b. Supplied as a milky-white colored aqueous dispersion.
c. A 1:5 mixture forms a clear, viscous, solution.
d. A 1:2 mixture forms a clear or slightly opalescent, viscous liquid.
e. A 1 part of both *Eudragit RL 30 D* and *Eudragit RS 30 D* dissolve completely in 5 parts acetone, ethanol or propan-2-ol to form a clear or slightly turbid solution. However, when mixed in a ratio of 1:5 with methanol, *Eudragit RL 30 D* dissolves completely, whereas *Eudragit RS 30 D* only partially.

11. Stability and Storage Conditions

Dry powder polymer forms are stable at temperatures less than 30°C. Above this temperature, powders tend to form clumps although this does not affect the quality of the substance and the clumps can be readily broken up. Dry powders are stable for at least two years if stored in a tightly closed container at less than 30°C.

Dispersions are sensitive to extreme temperatures and phase separation occurs below 0°C. Dispersions should therefore be stored at temperatures between 5-25°C and are stable for at least one year after shipping from the manufacturer's warehouse if stored in a tightly closed container at the above conditions.

12. Incompatibilities

Incompatibilities occur with certain polymethacrylate dispersions depending upon the ionic and physical properties of the polymer and solvent. For example, coagulation may be caused by soluble electrolytes, pH changes, some organic solvents and extremes of temperature, *see* Table II. Dispersions of *Eudragit L 30 D, RL 30 D, L 100-55* and *RS 30 D* are also incompatible with magnesium stearate.

Interactions between polymethacrylates and some drugs can occur although solid polymethacrylates and organic solutions are generally more compatible than aqueous dispersions.

13. Method of Manufacture

Prepared by the polymerization of acrylic and methacrylic acids or their esters, e.g. butyl ester or dimethylaminoethyl ester.

14. Safety

Polymethacrylate copolymers are widely used as film coating materials in oral pharmaceutical formulations. They are also used to a lesser extent in topical formulations and are generally regarded as nontoxic and nonirritant materials.

A daily intake of 2 mg/kg body-weight of *Eudragit* (equivalent to approximately 150 mg for an average adult) may be regarded as essentially safe in humans.

See also Section 15.

Table III: Summary of properties and uses of commercially available polymethacrylates (*Eudragit*, Röhm Pharma GmbH).

Type	Supply form	Polymer dry weight content	Recommended solvents or diluents	Solubility	Applications
Eudragit E 12.5	Organic solution	12.5%	Acetone, alcohols	Soluble in gastric fluid to pH 5	Film coating
Eudragit E 100	Granules	98%	Acetone, alcohols	Soluble in gastric fluid to pH 5	Film coating
Eudragit L 12.5 P	Organic solution	12.5%	Acetone, alcohols	Soluble in intestinal fluid from pH 6	Enteric coatings
Eudragit L 12.5	Organic solution	12.5%	Acetone, alcohols	Soluble in intestinal fluid from pH 6	Enteric coatings
Eudragit L 100	Powder	95%	Acetone, alcohols	Soluble in intestinal fluid from pH 6	Enteric coatings
Eudragit L 100-55	Powder	95%	Acetone, alcohols	Soluble in intestinal fluid from pH 5.5	Enteric coatings
Eudragit L 30 D-55	Aqueous dispersion	30%	Water	Soluble in intestinal fluid from pH 5.5	Enteric coatings
Eudragit S 12.5 P	Organic solution	12.5%	Acetone, alcohols	Soluble in intestinal fluid from pH 7	Enteric coatings
Eudragit S 12.5	Organic solution	12.5%	Acetone, alcohols	Soluble in intestinal fluid from pH 7	Enteric coatings
Eudragit S 100	Powder fluid	95%	Acetone, alcohols	Soluble in intestinal from pH 7	Enteric coatings
Eudragit RL 12.5	Organic solution	12.5%	Acetone, alcohols	High permeability	Sustained release
Eudragit RL 100	Granules	97%	Acetone, alcohols	High permeability	Sustained release
Eudragit RL PO	Powder	97%	Acetone, alcohols	High permeability	Sustained release
Eudragit RL 30 D	Aqueous dispersion	30%	Water	High permeability	Sustained release
Eudragit RS 12.5	Organic solution	12.5%	Acetone, alcohols	Low permeability	Sustained release
Eudragit RS 100	Granules	97%	Acetone, alcohols	Low permeability	Sustained release
Eudragit RS PO	Powder	97%	Acetone, alcohols	Low permeability	Sustained release
Eudragit RS 30 D	Aqueous dispersion	30%	Water	Low permeability	Sustained release
Eudragit NE 30 D	Aqueous dispersion	30% or 40%	Water	Swellable, permeable	Sustained release, tablet matrix

Note: Recommended plasticizers for the above types of *Eudragit* polymers include dibutyl phthalate, polyethylene glycols and triethyl citrate. Approximately 20% plasticizer is required for *Eudragit RL 30 D* and *Eudragit RS 30 D*. A plasticizer is not necessary with *Eudragit E 12.5*, *Eudragit E 100* and *Eudragit NE 30 D*.

15. Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Additional measures should be taken when handling organic solutions of polymethacrylates. Eye protection, gloves and a dust mask or respirator are recommended. Polymethacrylates should be handled in a well-ventilated environment and measures taken to prevent dust formation.

Acute and chronic adverse effects have been observed in workers handling the related substances methyl methacrylate and poly(methyl methacrylate) (PMMA).[12,13] In the UK, the occupational exposure limit for methyl methacrylate has been set at 410 mg/m^3 (100 ppm) long-term (8-hour TWA), and 510 mg/m^3 (125 ppm) short-term.[14]

See also Section 18.

16. Regulatory Status

Included in the FDA Inactive Ingredients Guide (oral capsules and tablets). Included in nonparenteral medicines licensed in the UK.

17. Pharmacopeias

Fr and USPNF.

18. Related Substances

Methyl methacrylate; poly(methyl methacrylate).

Methyl methacrylate: $C_5H_8O_2$
Molecular weight: 100.13
CAS number: [80-62-6]
Synonyms: methacrylic acid, methyl ester; methyl 2-methacrylate; methyl 2-methylpropenoate; MME.
Comments: methyl methacrylate forms the basis of acrylic bone cements used in orthopaedic surgery.

Poly(methyl methacrylate): $(C_5H_8O_2)_n$
Synonyms: methyl methacrylate polymer; PMMA.
Comments: poly(methyl methacrylate) has been used as a material for intra-ocular lenses, for denture bases and as a cement for dental prostheses.

19. Comments

A number of different polymethacrylates are commercially available which have different applications and properties, *see* Table III.

For spray-coating, polymer solutions and dispersions should be diluted with suitable solvents. Some products need the addition of a plasticizer such as: dibutyl sebacate; dibutyl phthalate; glyceryl triacetate and polyethylene glycol. Different types of plasticizer may be mixed to optimize the polymer properties for special requirements.

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22. Authors

USA: AJ Shukla.

Talc

1. Nonproprietary Names

BP: Purified talc
PhEur: Talcum
USP: Talc

2. Synonyms

E553b; *Magsil Osmanthus*; *Magsil Star*; powdered talc; purified French chalk; *Purtalc*; soapstone; steatite.

3. Chemical Name and CAS Registry Number

Talc [14807-96-6]

4. Empirical Formula Molecular Weight

Talc is a purified, hydrated, magnesium silicate, approximating to the formula $Mg_6(Si_2O_5)_4(OH)_4$. It may contain small, variable, amounts of aluminum silicate and iron.

5. Structural Formula

See Section 4.

6. Functional Category

Anticaking agent; glidant; tablet and capsule diluent; tablet and capsule lubricant.

7. Applications in Pharmaceutical Formulation or Technology

Talc is widely used in oral solid dosage formulations as a lubricant and diluent.[1,2] It is also used in topical preparations as a dusting powder, although it should not be used to dust surgical gloves, *see* Section 14. Since talc is a natural material it may frequently contain microorganisms and should therefore be sterilized when used as a dusting powder, *see* Section 11. Talc is additionally used to clarify liquids and is also used, mainly for its lubricant properties, in cosmetics and food products.

Use	Concentration (%)
Dusting powder	90-99
Glidant and tablet lubricant	1-10
Tablet and capsule diluent	5-30

8. Description

Talc is a very fine, white to grayish-white colored, odorless, impalpable, unctuous, crystalline powder. It adheres readily to the skin, is soft to the touch, and free from grittiness.

9. Pharmacopeial Specifications

Test	PhEur 1985	USP XXII
Identification	+	+
Microbial limit	⩽ 100/g	⩽ 500/g
Loss on ignition	—	⩽ 6.5%
Loss on drying	⩽ 1.0%	—
Readily carbonizable substances	+	—
Acid-soluble substances	+	⩽ 2.0%
Reaction and soluble substances	—	⩽ 0.1%
Water-soluble iron	—	+
Arsenic	—	⩽ 3 ppm
Calcium	⩽ 0.6%	—
Carbonate	+	—
Chloride	⩽ 140 ppm	—
Heavy metals	—	⩽ 0.004%
Lead	—	⩽

10. Typical Properties

Acidity/alkalinity:
pH = 6.5-10 for a 20% w/v aqueous dispersion.
Density (bulk & tapped): *see* HPE Data.
Hardness (Mohs): 1-1.5
Hygroscopicity: talc absorbs insignificant amounts of water at 25°C and relative humidities up to about 90%.
Particle size distribution: varies with the source and grade of material. Two typical grades are, ⩾ 99% through a 74 μm (#200 mesh) or ⩾ 99% through a 44 μm (#325 mesh). *See also* HPE Data.
Refractive index: n_D^{20} = 1.54-1.59
Solubility: practically insoluble in dilute acids and alkalis, organic solvents, and water.
Specific gravity: 2.7-2.8
Specific surface area: 12 m^2/g

	HPE Laboratory Project Data		
	Method	Lab #	Results
Bulk/tap density	BTD-1	1	B: 0.538 g/cm³ [a] T: 0.862 g/cm³
	BTD-1	1	B: 0.510 g/cm³ [a] T: 0.833 g/cm³
	BTD-1	1	B: 0.439 g/cm³ [b] T: 0.694 g/cm³
	BTD-1	1	B: 0.417 g/cm³ [c] T: 0.667 g/cm³
	BTD-7	14	B: 0.570 g/cm³ [a] T: 0.710 g/cm³
	BTD-7	14	B: 0.530 g/cm³ [a] T: 0.610 g/cm³
Compressibility	COM-1	21	No compacts [c]
	COM-7	12	No compacts [d]
Moisture content	MC-13	18	0.163% [a]
	MC-13	18	0.239% [a]
Particle size	PSD-5A	21	*See* Fig. 1.[e]

Supplier: a. Charles B Chrystal Co; b. Morelan; c. Whittaker, Clark & Daniels Inc; d. Pfizer Inc; e. Bate Chemical Co (Lot No.: A2349).

11. Stability and Storage Conditions

Talc is a stable material and may be sterilized by heating at 160°C for not less than 1 hour. It may also be sterilized by exposure to ethylene oxide or gamma irradiation.[3]
Talc should be stored in a well-closed container in a cool, dry, place.

12. Incompatibilities

Incompatible with quaternary ammonium compounds.

Colloidal Silicon Dioxide

1. Nonproprietary Names

BP: Colloidal anhydrous silica
PhEur: Silica colloidalis anhydrica
USPNF: Colloidal silicon dioxide

2. Synonyms

Aerosil; *Cab-O-Sil*; colloidal silica; fumed silica; light anhydrous silicic acid; silicic anhydride; silicon dioxide fumed; *Wacker HDK*.

3. Chemical Name and CAS Registry Number

Silica [7631-86-9]

4. Empirical Formula and Molecular Weight

Empirical Formula	Molecular Weight
SiO_2	60.08

5. Structural Formula

SiO_2

6. Functional Category

Adsorbent; anticaking agent; glidant; suspending agent; tablet disintegrant; viscosity-increasing agent.

7. Applications in Pharmaceutical Formulation or Technology

Colloidal silicon dioxide is widely used in pharmaceuticals, cosmetics and food products. Its small particle size and large specific surface area give it desirable flow characteristics which are exploited to improve the flow properties of dry powders in a number of processes, e.g. tableting.[1-3]

Colloidal silicon dioxide is also used to stabilize emulsions and as a thixotropic thickening and suspending agent in gels and semisolid preparations.[4] With other ingredients of similar refractive index transparent gels may be formed. The degree of viscosity increase depends on the polarity of the liquid (polar liquids generally require a greater concentration of colloidal silicon dioxide than nonpolar liquids). Viscosity is largely independent of temperature. However, changes to the pH of a system may affect the viscosity, *see* Section 11.

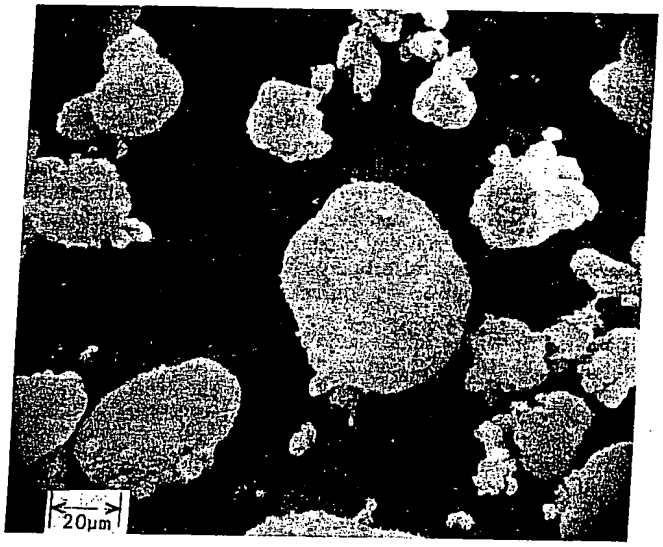
In aerosols, other than those for inhalation, colloidal silicon dioxide is used to promote particulate suspension, eliminate hard settling and minimize the clogging of spray nozzles. Colloidal silicon dioxide is also used as a tablet disintegrant and as an adsorbent dispersing agent for liquids in powders or suppositories.[5]

Use	Concentration (%)
Aerosols	0.5-2
Emulsion stabilizer	1-5
Glidant	0.1-0.5
Suspending and thickening agent	2-10

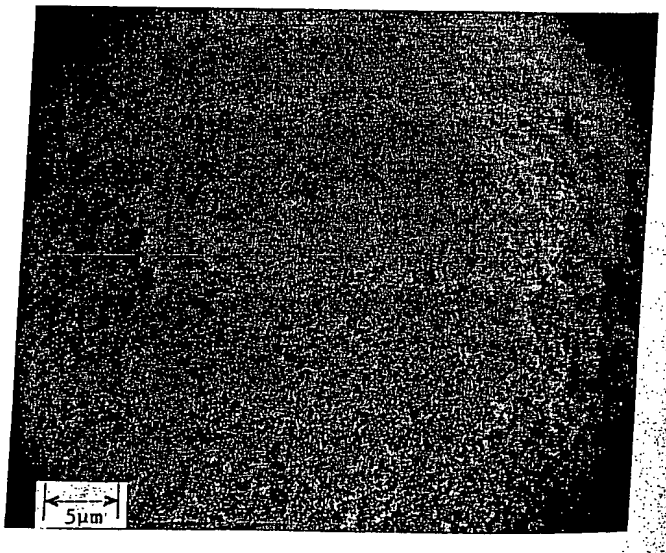
8. Description

Colloidal silicon dioxide is a submicroscopic fumed silica with a particle size of about 15 nm. It is a light, loose, bluish-white colored, odorless, tasteless, nongritty amorphous powder.

SEM: 1
Excipient: Colloidal silicon dioxide (*Aerosil A-200*)
Manufacturer: Degussa
Lot No.: 87A-1 (04169C)
Magnification: 600x
Voltage: 20 kV



SEM: 2
Excipient: Colloidal silicon dioxide (*Aerosil A-200*)
Manufacturer: Degussa
Lot No.: 87A-1 (04169C)
Magnification: 2400x
Voltage: 20 kV



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Hydrophobic Silica

Product	Description
Dumasil 100-FG	A water repellent, micro-fine silica treated with an organic silicone fluid. It is easily dispersed in organic systems. It finds application in defoamers, rubber, fire extinguishers, and food, dairy and vegetable processing.
Dumasil 100-Z-FG	
Dumasil 300-FG	

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Supplier	Product	Technical Summary
Degussa: Silicas	Aerosil R 810	Product specifications only. Includes spec range for: avg. primary particle size; specific gravity; surface area; loss on drying; pH-value; ignition loss; silicon dioxide; arsenic; Al2O3; Fe2O3; TiO2; HCl Content. Average primary particle size: 14 nm.; Surface area: 100-140 sq.-m/g.
Degussa: Silicas	Aerosil R 810S	Product specifications only. Includes spec range for: avg. primary particle size; specific gravity; surface area; loss on drying; pH-value; ignition loss; silicon dioxide; arsenic; Al2O3; Fe2O3; TiO2; HCl Content. Average primary particle size:14 nm.; Surface area: 110-130 sq.-m/g.
Degussa: Silicas	Aerosil R 811	Product specifications only. Includes spec range for: avg. primary particle size; specific gravity; surface area; loss on drying; pH-value; ignition loss; silicon dioxide; arsenic; Al2O3; Fe2O3; TiO2; HCl Content. Average primary particle size: 12 nm.; Surface area:150-190 sq.-m/g.
Degussa: Silicas	Aerosil R 812 S vv60; vv90	Hydrophobic Fumed Silica, Hexamethyl Disilazane Aerosil 300 treated, BET surface area=150+/-25m2/g, Average primary particle size=7nm. (Available in VS, densified grade.) Aerosil R 812 S is double treated and is much more hydrophobic than the regular R 812. Mainly used in high solids coatings because it will give less visc. increase than R 812
Degussa: Silicas	Aerosil R 812 vv60; vv90	Hydrophobic Fumed Silica, Hexamethyl Disilazane Aerosil 300 treated, BET surface area=150+/-25m2/g, Average primary particle size=7nm. (Available in VS, densified grade.)
Degussa: Silicas	Aerosil R 816 vv60; vv90	Product specifications only. Includes spec range for: avg. primary particle size; specific gravity; surface area; loss on drying; pH-value; ignition loss; silicon dioxide; arsenic; Al2O3; Fe2O3; TiO2; HCl Content. Average primary particle size: 12 nm.; Surface area: 180 sq.-m/g.
Degussa: Silicas	Aerosil R 8200	Product specifications only. Includes spec range for: avg. primary particle size; specific gravity; surface area; loss on drying; pH-value; ignition loss; silicon dioxide; arsenic; Al2O3; Fe2O3; TiO2; HCl Content. Average primary particle size:? nm.; Surface area: 135-185 sq.-m/g.
Degussa: Silicas	Aerosil R 972	Hydrophobic Fumed Silica, Dimethyl Dichlorosilane Aerosil 130 treated, BET surface area=110+/-20m2/g, Average primary particle size=16nm. Densified grade (VS) is also available.
Degussa: Silicas	Aerosil R 972V	Product specifications only. Includes spec range for: avg. primary particle size; specific gravity; surface area; loss on drying; pH-value; ignition loss; silicon dioxide; arsenic; Al2O3; Fe2O3; TiO2; HCl Content. Average primary particle size: 16 nm.; Surface area: 90-130 sq.-m/g.
Degussa: Silicas	Aerosil R 974	Hydrophobic Fumed Silica, Dimethyl Dichlorosilane Aerosil 200 treated, BET surface area=170+/-20m2/g, Average primary particle size=12nm. Densified grade (V) & (VS) are also available.

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